IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: MERCK MUMPS VACCINE ANTITRUST LITIGATION	Master File No. 2:12-cv-03555
THIS DOCUMENT RELATES TO: ALL ACTIONS.	

MEMORANDUM OF LAW IN SUPPORT OF MERCK & CO., INC.'S MOTION TO DISMISS PLAINTIFFS' AMENDED COMPLAINT

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I. INTRODUCTION

Seeking treble damages on behalf of themselves and a putative nationwide class of every direct purchaser of the mumps vaccine over the course of more than a decade, Plaintiffs Chatom Primary Care, P.C., Andrew Klein, M.D., and John I. Sutter, M.D. ("collectively, "Plaintiffs"), essentially duplicate the allegations in *United States ex rel. Krahling v. Merck & Co., Inc.*, 2:10-cv-04374 CDJ (E.D. Pa.) ("the *qui tam* action"). Plaintiffs assert that those allegations form a basis for claims against Merck & Co., Inc. ("Merck") for: (1) monopolizing a market for mumps vaccines in violation of Section 2 of the Sherman Act; (2) violating 25 different state consumer protection laws; (3) breaching unidentified contracts with Plaintiffs and the putative class; (4) unjustly enriching itself; and (5) breaching warranties under the Uniform Commercial Code, as adopted in Pennsylvania.

The central allegation in each of Plaintiffs' claims is that Merck falsified test data regarding the efficacy of the mumps component of its measles, mumps, and rubella ("MMR") vaccine, and reported that data to the Food and Drug Administration ("FDA"), and as a result, the efficacy information in the FDA-approved vaccine labeling is false and misleading. Plaintiffs contend that those alleged false statements foreclosed the U.S. market for mumps vaccines to competition because potential rivals were deterred from entry and, as a result, Plaintiffs and members of the putative class paid artificially high prices for the mumps vaccine. Plaintiffs' claims fail as a matter of law and should be dismissed for the following reasons:

First, Section 2 of the Sherman Act reaches only unilateral conduct by a firm with market power that is deemed exclusionary, *i.e.*, coercive conduct that harms competition by restricting output and raising prices. Plaintiffs do not allege in connection with their claim for monopolization under Section 2 of the Sherman Act (First Claim for Relief) that Merck engaged in any affirmative conduct that traditionally has been recognized by the courts as exclusionary,

such as predatory pricing, exclusive dealing, or a refusal to deal. Instead, Plaintiffs base their Section 2 claim entirely on allegedly false statements made by Merck about the efficacy of its mumps vaccine, which they say deterred entry into the mumps vaccine market. It is well-established, however, that statements – even false statements – by an alleged monopolist about the quality of its own product do not harm competition by raising prices or curtailing output and thus cannot form the basis for antitrust liability under Sherman Act Section 2.

Second, Plaintiffs' Sherman Act claim and its remaining state law claims, which are all based on Merck's alleged mislabeling of its mumps vaccine, must be dismissed because they seek to assert private causes of action for relief under the Food, Drug, and Cosmetic Act ("FDCA"), 31 U.S.C. § 301 *et seq.* The FDCA and its implementing regulations set forth a comprehensive regulatory scheme pertaining to vaccine labeling, the enforcement of which is the exclusive province of the FDA. To permit private litigants like Plaintiffs to, in effect, usurp the FDA's authority and enforce the FDCA through federal and state law claims that purport to assert a "fraud-on-FDA" theory would inevitably interfere with the FDA's enforcement priorities and objectives. Plaintiffs' Sherman Act claim is therefore precluded and their state law claims are preempted and should be dismissed.

Third, Plaintiffs' attempt to allege in catch-all fashion that Merck violated the consumer protection laws of 25 separate jurisdictions without alleging facts specific to any one of those statutes does not even meet the most basic pleading requirements, and should be dismissed on that basis alone. But even putting that fatal defect aside, Plaintiffs – who are residents of Alabama, New York and New Jersey – lack standing to bring claims under the consumer protection laws of the states where they do not reside and could not possibly have suffered injury. Moreover, even under the consumer protection laws applicable in the states where

Plaintiffs reside, their allegations are plainly insufficient to state viable claims, and therefore Plaintiffs' Third Claim for Relief should be dismissed in total.

Fourth, Plaintiffs' claims for breach of express and implied warranty under Pennsylvania law (Fourth and Fifth Claims for Relief) are likewise deficient. As a matter of law, statements contained in Merck's product packaging, which are required by statute, cannot create an express warranty. Nor could Merck's marketing and advertising have created an express warranty in the absence of factual allegations that such statements were specifically directed to any named Plaintiff and that those statements induced reliance. Plaintiffs' implied warranty claim also fails because Plaintiffs have not alleged that the vaccine was defective, *i.e.*, that it failed to prevent the mumps virus. Absent plausible allegations that Merck's mumps vaccine did not perform as intended, Plaintiffs' breach of implied warranty claim fails.

Fifth, Plaintiffs' breach of contract claim (Third Claim for Relief) should be dismissed because Plaintiffs fail to allege facts sufficient to support the elements of a breach of contract claim. Plaintiffs' allegations on each element are far too conclusory. Plaintiffs also have not identified the applicable state law governing the breach of contract claim, which warrants dismissal as a matter of law.

Sixth, Plaintiffs cannot prevail on their unjust enrichment claim (Sixth Claim for Relief) because they have failed to allege sufficient facts supporting that claim. Besides that, Plaintiffs have expressly alleged the existence of a written agreement between them and Merck, and where a written agreement exists, a claim for unjust enrichment cannot. Finally, Plaintiffs have again failed to identify the state law under which they purport to be proceeding. Plaintiffs' unjust enrichment claim thus should be dismissed as a matter of law.

II. FACTUAL BACKGROUND

Merck is a pharmaceutical company whose vaccine division is located in Pennsylvania. Am. Compl. ¶ 15 (Doc. No. 26). Merck first developed a mumps vaccine in the 1960s based on a mumps strain that infected the daughter of its principal vaccine researcher. *Id.* ¶ 24. In 1967, after conducting field studies establishing that the vaccine was 95 percent effective, Merck obtained approval to sell the vaccine from the Division of Biologics Standards of the National Institutes of Health, the government agency at the time responsible for licensing. *Id.* ¶¶ 24, 34.

Today, the mumps vaccine is subject to regulation by the FDA and cannot be sold without FDA approval. The labeling of the vaccine is also subject to strict oversight and approval by the FDA. Contrary to Plaintiffs' central contention, *see id.* ¶ 85, the label does not now and has never stated any particular efficacy rate. Instead, the label states that "in a series of double-blind controlled field studies" the vaccine demonstrated "a high degree of protective efficacy." *See* MMR Label (attached as "Exhibit A"); *see also United States ex rel. Krahling v. Merck & Co., Inc.*, 2:10-cv-04374 CDJ (E.D. Pa.), Brief in Support of Mot. to Dismiss (Docket Entry No. 45) ("Krahling Motion to Dismiss") at 6-8. Merck's mumps vaccine continues to be administered widely in the United States, due in part to school vaccination requirements. Am. Compl. ¶ 33. At least one other company, GlaxoSmithKline ("GSK"), has developed a mumps vaccine, which it markets in Europe, Canada, and Australia. *Id.* ¶ 113.

In *United States ex rel. Krahling v. Merck & Co., Inc.*, 2:10-cv-04374 CDJ (E.D. Pa.), relators brought a *qui tam* action against Merck claiming that it had misrepresented the efficacy rate of the mumps component of MMR and had provided the FDA false information about the efficacy testing. The *qui tam* action was unsealed in June 2012. Plaintiffs' claims in this putative class action closely followed the unsealing of the *qui tam* action, and rely almost exclusively on the *qui tam* relators' allegations. Plaintiffs' Complaint alleges, among other

things, that Merck's mumps vaccine has become less effective over the years. *Id.* ¶¶ 2, 11, 27, 86, 115, 174. It claims that mumps outbreaks occurred in 2006 and 2009 as a result of the vaccine's diminished efficacy. *Id.* ¶¶ 96-110. Despite these allegations, Plaintiffs never plead what they believe the vaccine's true efficacy rate to be.

The three named Plaintiffs in this putative class action are all health-care providers: physicians Andrew Klein, M.D. ("Klein") and John I. Sutter, M.D. ("Sutter"), and Chatom Primary Care, P.C. ("Chatom"). Klein is alleged to be a resident of New York, Sutter a resident of New Jersey, and Chatom an Alabama corporation. *Id.* ¶¶ 12-14. The Complaint alleges that all three Plaintiffs purchased mumps vaccine from Merck. *Id.* Other than alleging that their purchases occurred during the class period, which runs from 1999 to the present, *see id.* ¶ 128, there is no allegation as to when any of the Plaintiffs purchased the vaccine. There is also no allegation as to how much vaccine they purchased or how much they paid for it. Although the Complaint does not even allege what the Plaintiffs did with the vaccine they purchased, it may be inferred from the fact that they are healthcare providers that they administered the vaccine to patients. The Complaint does not allege that any of Plaintiffs' patients were harmed by Merck's mumps vaccine, or that any of Plaintiffs' patients were not adequately protected by the vaccine. Nor does the Complaint allege that a single patient to whom Plaintiffs administered Merck's mumps vaccine contracted mumps. Instead, the only harm alleged in the Complaint is economic: Plaintiffs allege they overpaid for the vaccine as a result of Merck's conduct.[1]

Based entirely on the *qui tam* relators' allegations, including that the vaccine's effectiveness had significantly diminished to "far less" than represented by Merck, *see, e.g., id.* ¶

[1] Because healthcare providers, like Plaintiffs, are reimbursed for vaccines they administer by patients, insurance companies, and government programs such as Medicaid, it is possible that any potential economic loss has been fully mitigated, so that Plaintiffs have actually suffered no damages at all.

174, and that Merck falsified test data to inflate the efficacy of its mumps vaccine, Plaintiffs allege that Merck monopolized the market for mumps vaccines and, through representations made in the vaccine's label, violated consumer protection statutes, breached warranties and contracts, and was unjustly enriched. Plaintiffs' attempt to impose new legal theories on the allegations previously set forth in the *qui tam* complaint, about which the FDA has already been notified and has already conducted an investigation, cannot survive a motion to dismiss for the reasons set forth below.

III. STANDARD OF REVIEW

The Supreme Court held in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), that a pleading offering mere "labels and conclusions" or "a formulaic recitation of the elements of a cause of action" must not survive a Fed. R. Civ. P. 12(b)(6) motion. *Id.* at 555 (citation omitted). Instead, to survive a motion to dismiss, a complaint "must contain sufficient *factual matter* . . . to 'state a claim for relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Twombly*, 550 U.S. at 570) (emphasis added). In determining whether a plaintiff has stated a plausible claim for relief, courts in the Third Circuit apply a three part test:

> First, the court must tak[e] note of the elements a plaintiff must plead to state a claim. Second, the court should identify allegations that, because they are no more than conclusions, are not entitled to the assumption of truth. Finally, where there are well-pleaded factual allegations, a court should assume their veracity and then determine whether they plausibly give rise to an entitlement for relief.

Santiago v. Warminster Twp., 629 F.3d 121, 130 (3d Cir. 2010) (internal quotations and citation omitted).

Under the Third Circuit's particular formulation of the plausibility standard, the court must, on a Rule 12 motion, weigh competing inferences drawn from the allegations of the complaint, and if an inference of illegality is no more likely than an inference of permissible conduct, the complaint must be dismissed. *Burtch v. Milberg Factors, Inc.*, 662 F.3d 212, 228

(3d Cir. 2011). Weighing such inferences is a "context-specific task that requires the reviewing court to draw on its judicial experience and common sense." *Iqbal*, 556 U.S at 679 (citation omitted). Because "context matters" in determining whether a pleading can survive a Rule 12 challenge, "what suffices to withstand a motion to dismiss necessarily depends on substantive law and the elements of the specific claim asserted." *In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300, 320 n.18 (3d Cir. 2010) (citation omitted). Hence, "[s]ome claims will demand relatively more factual detail to satisfy th[e] [plausibility] standard, while others require less" depending on the underlying substantive law. *Id.* (citation omitted). The underlying legal doctrine is particularly critical where, as here, the Plaintiffs have asserted claims under the Sherman Act because "antitrust law limits the range of permissible inferences from ambiguous evidence." *Id.* (citing *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 588 (1986)) (internal quotations omitted). Thus, in antitrust cases, more factual amplification may be needed in light of "common economic experience." *Id.* at 320 n.18, 326 (internal quotations omitted).

Claims such as Plaintiffs' here, which are predicated on fraud, are subject to an even more stringent pleading obligation under Fed. R. Civ. P. 9(b). *See, e.g.*, *Lum v. Bank of Am.*, 361 F.3d 217, 228 (3d Cir. 2004) (exacting pleading standard prescribed by Rule 9(b) applies to antitrust claims sounding in fraud), *abrogated in part on other grounds by Twombly*, 550 U.S. 544, *as recognized in In re Ins. Brokerage Antitrust Litig.*, 618 F.3d 300; *FDIC v. Bathgate*, 27 F.3d 850, 876 (3d Cir. 1994) (pleading requirements of Rule 9(b) apply to claims based on state consumer fraud statutes). Rule 9(b) commands that "[i]n alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake." Said differently, Rule 9(b) imposes a burden on the plaintiff to allege a description of the "'who, what, when, where

and how' of the events at issue." *In re Rockefeller Ctr. Props., Inc. Secs. Litig.*, 311 F.3d 198, 217 (3d Cir. 2002) (citations omitted). This means that, when asserting a claim predicated on fraud, a claimant must "plead (1) a specific false representation of material fact; (2) knowledge by the person who made it of its falsity; (3) ignorance of its falsity by the person to whom it was made; (4) the intention that it should be acted upon; and (5) that the plaintiff acted upon it to his damage." *Shapiro v. UJB Fin. Corp.*, 964 F.2d 272, 284 (3d Cir. 1992) (citation omitted).

In a putative class action complaint, it is appropriate to "determine if Plaintiffs have stated a claim under the laws of jurisdictions where they reside or do business, because at least one named plaintiff must have a cause of action on a claim for that claim to survive a motion to dismiss." *In re Flonase Antitrust Litig.*, 610 F. Supp. 2d 409, 414 (E.D. Pa. 2009).

Here, Plaintiffs have not alleged sufficient facts to "nudge[] [their] claims" over the line from "[merely] conceivable to plausible," and Plaintiffs' claims must be dismissed. *See Iqbal*, 556 U.S. at 680 (internal quotations omitted).

IV. LEGAL ARGUMENT

A. Plaintiffs' Monopolization Claim Must Be Dismissed.

Plaintiffs' monopolization claim under Section 2 of the Sherman Act is deficient as a matter of law and must be dismissed for three distinct reasons. First, Plaintiffs fail to allege that Merck engaged in any coercive exclusionary conduct. Second, as addressed thoroughly in Merck's motion to dismiss the Krahling *qui tam* complaint, Plaintiffs may not pursue private claims that are premised on the theory that Merck committed fraud on the FDA. And third, the Complaint is devoid of any plausible allegation making a causal connection between Merck's alleged misconduct and Plaintiffs' alleged antitrust injury.

1. Plaintiffs Do Not Allege That Merck Engaged in Any Coercive Exclusionary Conduct.

Having a monopoly, as Plaintiffs claim Merck does in this case, does not itself violate Section 2 of the Sherman Act. *Verizon Commc'ns v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 407 (2004). Instead, a viable claim for monopolization must be predicated on the existence of monopoly power *and* anticompetitive or "exclusionary conduct" that harms the competitive process by obstructing "the achievement of competition's basic goals – lower prices, better products, and more efficient production methods." *Town of Concord v. Boston Edison Co.*, 915 F.2d 17, 21-22 (1st Cir. 1990) (citations omitted). Absent plausible allegations that an alleged monopolist engaged in affirmative conduct obstructing competition, a claim under Section 2 of the Sherman Act cannot survive. *See, e.g.*, *Oce N. Am. v. MCS Servs., Inc.*, 795 F. Supp. 2d 337, 345 (D. Md. 2011) (granting Rule 12 motion because false statements could not give rise to a plausible claim for actual or attempted monopolization).

Recognized forms of exclusionary conduct sufficient to sustain a claim for monopolization include: (1) refusals to deal with customers or suppliers;[2] (2) denial of access to rivals;[3] (3) exclusive dealing;[4] (4) tying;[5] (5) below cost loyalty discounts;[6] (6) bundled

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[2] *Lorain Journal Co. v. United States*, 342 U.S. 143 (1951); *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181 (3d Cir. 2005).

[3] *Verizon*, 540 U.S. 398; *Aspen Skiing Co. v. Aspen Highlands Skiing Corp.*, 472 U.S. 585 (1985).

[4] *Race Tires Am., Inc. v. Hoosier Racing Tire Corp.*, 614 F.3d 57 (3d Cir. 2010); *Dentsply Int'l*, 399 F.3d 181; *LePage's Inc. v. 3M*, 324 F.3d 141 (3d Cir. 2003) (en banc); *United States v. Microsoft*, 253 F.3d 34 (D.C. Cir. 2001); *United States v. United Shoe Mach. Co.*, 110 F. Supp. 295 (D. Mass. 1953), *aff'd*, 347 U.S. 521 (1954) (per curiam).

[5] *Microsoft*, 253 F.3d 34.

[6] *LePage's*, 324 F.3d 141.

discounts;[7] (7) predatory pricing;[8] and (8) predatory hiring.[9] Each of these recognized forms of exclusion share the common characteristic that they impose tangible obstacles to the competitive process and are, in some fashion, coercive.

The glaring defect in Plaintiffs' Complaint is that it nowhere alleges that Merck engaged in any conduct that has previously been recognized by the courts as coercive and thereby has an adverse effect on competition flowing from the coercive nature of the conduct. Rather, Plaintiffs' Complaint ignores the pervasive judicial concern about extending the antitrust laws beyond their permissible scope. Plaintiffs ask this Court to allow them to proceed on an unprecedented theory of antitrust liability predicated on non-coercive, allegedly false statements that Merck made about its own products. In particular, Plaintiffs allege that Merck "unlawfully monpoliz[ed] the U.S. market for Mumps Vaccine by . . . misrepresent[ing] . . . the true efficacy of its vaccine" and that "through its false representations . . . Merck has unlawfully monopolized the Relevant Market . . . " Am. Compl. ¶ 3, 111. But courts have consistently held that false statements such as those that Plaintiffs have pleaded are not actionable under Section 2, and thus, Plaintiffs' monopolization claim falls at this first hurdle. *See, e.g.*, *Sanderson v. Culligan Int'l Co.*, 415 F.3d 620, 623 (7th Cir. 2005) ("[a]ntitrust law condemns practices that drive up prices by curtailing output[,]" and"[f]alse statements . . . do not curtail output in either the short or long run") (internal citations omitted).

For the conduct of an accused monopolist to be anticompetitive within the meaning of Section 2 of the Sherman Act, it must have a coercive effect on customers or rivals, "break[ing]

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[7] *LePage's*, 324 F.3d 141; *SmithKline Corp. v. Eli Lilly & Co.*, 575 F.2d 1056, 1062 (3d Cir. 1978).

[8] *Brooke Group Ltd. v. Brown & Williamson Tobacco Corp.*, 509 U.S. 209 (1993); *Advo, Inc. v. Phila. Newspapers*, 51 F.3d 1191 (3d Cir. 1995).

[9] *West Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85 (3d Cir. 2010); *Universal Analytics, Inc. v. MacNeal-Schwendler Corp*., 914 F.2d 1256 (9th Cir. 1990).

the competitive mechanism and depriv[ing] customers of the ability to make a meaningful choice." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 285 (3d Cir. 2012) (citations omitted). A monopolist's conduct is coercive only when it "effectively forces" customers to make a decision, *see LePage's Inc.* 324 F.3d at 159 (2003) (en banc), or "imposes" a policy on customers that prevents them from freely making their own economic decisions, *see Dentsply Int'l, Inc.*, 399 F.3d at, 184. Simply put, coercion entails "exclusionary conduct [that] leaves the consumer with no input whatever." *Stearns Airport Equip. Co. v. FMC Corp.*, 170 F.3d 518, 525 (5th Cir. 1999). Thus, the Third Circuit held in *Santana Prods., Inc. v. Bobrick Washroom Equip., Inc.*, 401 F.3d 123, 132-35 (3d Cir. 2005), that allegedly false statements – even supposed disparagement by an alleged monopolist concerning a *rivals' goods* did not satisfy the "exclusionary conduct" requirement of Section 2 of the Sherman Act because those statements had no coercive effect, which is the *sine qua non* of Section 2 liability. In *Santana*, much like here, the plaintiff did not allege any coercive measures by the defendant that would have prevented a competitor from selling its products to any willing customers or prevented customers from choosing to deal with that competitor. *Id.* at 132. The defendant's fraudulent statements were, therefore, "irrelevant" for antitrust purposes, because "deception, reprehensible as it is, can be of no consequence so far as the Sherman Act is concerned." *Id.* (citations and quotations omitted). As the *Santana* court noted, without coercion, "the natural remedy would seem to be an increase in [competitors'] efforts on future [opportunities], not an antitrust suit." *Id.* at 133. The *Santana* court's reasoning effectively dooms Plaintiffs' Section 2 claim against Merck in this case.

Where, as here, the alleged false statements do not disparage a competitor's product or service, and instead pertain to the defendant's own products, the risk of harm to competition

from "product promotion" is zero. As the Fifth Circuit held in *Stearns Airport Equipment Co. v. FMC Corp.*, 170 F.3d 518 (5th Cir. 1999) – an opinion the *Santana* court deemed "instructive" – statements by a supplier about its own products to potential customers "may have been wrong, misleading, or debatable," but there could be no exclusion as long as the decision on the choice of a supplier remained "in the hands of the consumer" and rivals were free to promote their own goods. *Id.* at 524. Thus, the *Stearns* court held that alleged false statements made by an alleged monopolist promoting its own products by stressing its "technological superiority" cannot as a matter of law provide a viable predicate for Section 2 liability. *Id.* .

The requirement of an affirmative coercive action designed to impede competition can also be found in cases adjudicating so-called "fraudulent procurement" of patents under the Sherman Act. It has long been the case that relying on fraudulent statements to acquire intellectual property rights does not violate Section 2 of the Sherman Act unless and until the defendant actually attempts to enforce the fraudulently obtained IP rights and, even then, only if the attempted enforcement threatens competition in the relevant market. *See Walker Process Equip., Inc. v. Food Machinery & Chem. Corp.*, 382 U.S. 172, 177, 179 (1965); *Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc.* 375 F. 3d 1341, 1355 (Fed. Cir. 2004), *rev'd on other grounds*, 126 S. Ct. 980 (2006); *see also Hydril Co. LP v. Grant Prideco LP*, 474 F.3d 1344, 1350 (Fed. Cir. 2007) (competitor may proceed with Walker Process claim against patent holder where it alleged that patent was obtained by fraud ***and*** that patentee had threatened enforcement in writing because "[t]hreats of patent litigation . . . based on a fraudulently-procured patent, with a reasonable likelihood that such threats will cause the customers to cease dealing with [the competitor], is the kind of *economic coercion* that the antitrust laws are intended to prevent") (emphasis added). Thus, even if the fraudulent acquisition of a patent leads some competitors to

choose not to compete against the patent holder, that conduct standing alone is not, as a matter of law, an act of monopolization sufficient to support a Section 2 claim. For the same reason, Merck's alleged misrepresentations about the efficacy of its own product, standing alone, are not acts of monopolization regardless of how those alleged misrepresentations may have influenced competitors' choices because the hallmark coercive effects of the conduct are lacking.

While the overwhelming weight of authority regards any type of alleged false statements to be immaterial as far as the antitrust laws are concerned, courts in rare circumstances have considered a defendant's speech in assessing whether it engaged in "exclusionary conduct" for purposes of Section 2. The Third Circuit's view is that allegedly false statements may be pertinent – though not of themselves acts of monopolization – if those statements are defamatory (*i.e.*, they pertain to a rival or its products) and they are part of a broader course of coercive conduct. *See West Penn*, 627 F.3d at 109 n.14. In *West Penn*, the second-largest hospital system in the Pittsburgh area claimed that its larger rival made false statements to investors *and* engaged in a range of exclusive dealing, predatory hiring, and predatory refusals to deal – all conduct that has been recognized by the courts as coercive and independently actionable under Section 2. The statements at issue in *West Penn* present a stark contrast to the alleged statements that form the sole basis for Plaintiffs' Section 2 claim in this case. First, unlike Merck's supposed statements about its mumps vaccine, UMPC's alleged statements in *West Penn* were not about its own services. Second, the alleged false statements made by UPMC in *West Penn* were aimed at choking off plaintiff's ability to obtain essential financing and were made against the backdrop of independently actionable, exclusionary conduct designed to restrict output by eliminating an existing competitor. No similar facts have found their way into Plaintiffs' Complaint in this case, and that represents a dispositive flaw in Plaintiffs' Section 2 theory.

The defects in Plaintiffs' monopolization claim are readily apparent from their own allegations. Plaintiffs do not allege that Merck's supposed statements about the efficacy of the mumps component of its MMR vaccine, which are the sole basis for its Section 2 claim, coerced the FDA, any rival vaccine manufacturers, any members of the putative class, or anyone else. Quite the opposite – Plaintiffs expressly allege that the FDA and others undertook clinical reviews, investigations and assessments of Merck's submissions and vaccines. Am. Compl. ¶¶ 88, 100-07. Moreover, Plaintiffs do not allege that Merck's rivals were coerced by any of the alleged false statements, and the Complaint is devoid of allegations that those statements made entry impossible. On the contrary, Plaintiffs admit that a competing vaccine, Priorix, which is widely available in Canada, Europe, and Australia, has not been launched in the United States because its manufacturer, GSK, in its independent business judgment, decided not to expand.[10] *Id.* ¶ 113. This case, therefore, closely parallels *Schachar v. Am. Academy of Ophthalmology, Inc.*, 870 F.2d 397 (7th Cir. 1989), in which the court affirmed dismissal of the Section 2 claim because "when a [defendant] provides information . . . but does not constrain others to follow its recommendations, it does not violate the antitrust laws." *Id.* at 399-400 (citations omitted). The court observed that, "[i]f such [information] should be false or misleading or incomplete or just plain mistaken, the remedy is not antitrust litigation but more speech – the marketplace of ideas." *Id.* at 400.

[10] Putting aside whether Plaintiffs' allegation regarding GSK is accurate, facts of which this court may take judicial notice directly undermine Plaintiffs' central assertion that Merck's conduct somehow created a disincentive to new entry. It appears as if one or more vaccine manufacturers are presently seeking to compete with Merck's mumps vaccine in the United States. Publicly-available government information on the FDA's website indicates that as of November 1, 2011 – before any of the *qui tam* relators' allegations had been disclosed – "new live attenuated mumps vaccines are being submitted to FDA for approval." *See* http://www.fda.gov/BiologicsBloodVaccines/ScienceResearch/BiologicsResearchAreas/ucm127315.htm. A court may consider such publicly available information in addition to the allegations in the complaint, when deciding a motion to dismiss. *Pension Benefit Guar. Corp. v. White Consol. Indus., Inc.*, 998 F.2d 1192, 1196-97 (3d Cir. 1996).

Nor can Plaintiffs fill the void in their defective Section 2 claim by coupling together (a) false statements that cannot form the basis of a monopolization claim with (b) other forms of non-exclusionary conduct that also cannot independently form the basis of a viable claim under Section 2, in an attempt to "alchemize them into a new form of antitrust liability . . . " *Pacific Bell Tel. Co. v. Linkline Commc'ns, Inc.*, 555 U.S. 438, 457 (2009). As the Supreme Court has said, in the antitrust context, "two wrong claims do not make one that is right." *Id.*

Despite this controlling precedent, Plaintiffs attempt to fortify their otherwise anemic Section 2 claim with colorful allegations of improper testing techniques, falsification of data and employee intimidation, which are simply irrelevant to Plaintiffs' assertion that Merck monopolized a market for mumps vaccines in the United States. As the court held in *Briggs & Stratton Corp. v. Kohler Co.*, 405 F. Supp. 2d 986 (W.D. Wis. 2005), if the non-exclusionary conduct "is not connected intrinsically to a violation of antitrust law, it is not relevant to the antitrust claims at issue," and thus, "[a]ppending an irrelevant allegation . . . does not transform the raven into a swan." *Id.* at 990. In other words, "the Sherman Act does not reach conduct that is only unfair, impolite, or unethical" nor is it "a code of medical ethics or methodology . . . " *Schachar*, 870 F.2d at 399 (internal citation and quotation omitted). "Unless one group of suppliers diminishes another's ability to peddle its wares (technically, reduces rivals' elasticity of supply), there is not even the beginning of an antitrust case, no reason to investigate further to determine whether the restraint is 'reasonable.'" *Id.* Dismissal of Plaintiffs' Section 2 claim against Merck is therefore required.

2. Plaintiffs' Antitrust Claim Is an Impermissible Attempt to Pursue a Private Claim under the FDCA.

As Merck has demonstrated in the Krahling Motion to Dismiss, the FDA is the regulatory agency responsible for evaluating and approving the MMR vaccine labeling. Here, Plaintiffs'

claims, in their entirety, rely on the Krahling allegations that Merck defrauded the FDA in the submission of data as part of the FDA regulatory process. However, rules of FDA deference prohibit this Court from second-guessing the FDA and adjudicating a private citizen action based upon a "fraud on the FDA." *See* Krahling Motion to Dismiss at 15-28. Specifically, 21 U.S.C. § 337(a) provides that proceedings to enforce or restrain violations of the FDCA "shall be by and in the name of the United States." Accordingly, even where a cause of action against a manufacturer is not nominally brought under the FDCA, suits by private citizens may not be premised either on a manufacturer's fraud on the FDA or on a contention that a manufacturer has violated an FDA regulation. *See Buckman v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) (barring common law product liability cause of action that depended upon finding that defendant defrauded the FDA); *Sandoz Pharms. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990) (barring Lanham Act claim that depended upon finding that defendant's product violated FDA regulations); *see also Southeast Laborers Health & Welfare Fund v. Bayer Corp.*, 444 F. App'x 401 (11th Cir. 2011) (barring RICO and state consumer protection claims that depended upon finding that defendant defrauded the FDA). For this reason, as explained in depth in the Krahling Motion to Dimiss which is incorporated by reference here, Plaintiffs' private claims – in this case its federal Sherman Act claim – must be dismissed.

3. Plaintiffs Fail to Allege Plausible Proximate Causation.

In addition to constituting an improper encroachment on the FDA's authority, Plaintiffs' Sherman Act claim also depends upon speculation about the occurrence of multiple intervening events. The Amended Complaint speculates that if the FDA-approved labeling had read as Plaintiffs believe it should have read, other companies would have attempted to enter the U.S. mumps vaccine market. Am. Compl. ¶ 113. Plaintiffs plead no facts to support this allegation. Indeed, they plead many facts to refute it. For example, Plaintiffs allege that a GSK measles,

mumps and rubella vaccine is "widely sold in Europe" and other locations. *Id.* Plaintiffs also allege that Merck's MMR is sold in Europe. *Id.* ¶ 16. If Merck's representations regarding the effectiveness of the mumps component of the vaccine are the obstacle that prevents GSK from attempting to compete with Merck in the United States, why does GSK compete with Merck in Europe?

Plaintiffs also detail the "significant barriers" to entry into the vaccine market. *See id.* ¶ 30. They say:

> Vaccine production is a capital-intensive, fixed-costs-based business, with the average cost to bring a vaccine to market of about $700 million. Moreover, the research, development, testing, and government approval process is very expensive, time-consuming, and risky. Several years and millions of dollars might be spent on developing a new vaccine only to find it fail in the final stages of testing, or to have the government refuse to approve it or significantly limit its application or distribution.

Id. Plaintiffs even acknowledge that mumps is a "particularly risky" vaccine market to seek to enter. *Id.* ¶ 112. In the face of all of these allegations calling into question whether another manufacturer would attempt to enter the mumps vaccine market, Plaintiffs offer only speculation, with no supporting facts, for their contention that the statement on Merck labeling, that clinical studies had demonstrated a high degree of protective efficacy for the mumps component of MMR, foreclosed competition.

Proximate cause is further undermined by an additional speculative step on which they must rely. Plaintiffs admit that "Mumps Vaccine requires FDA licensing before it can be sold in the U.S." *Id.* ¶ 28. As noted above, they also admit that the government may "refuse to approve [a new vaccine] or significantly limit its application or distribution." *Id.* ¶ 30. The regulations governing the approval of vaccine licenses specify only that a license will be issued if the Director of FDA's Center for Biologics Evaluation finds that "the product meet[s] the applicable

requirements." 21 C.F.R. § 601.4; *see also* 21 C.F.R. § 601.20. As the Supreme Court has noted:

> The FDA has never even spelled out in regulations the criteria it uses to decide whether a vaccine is safe and effective for its intended use. And the decision is surely not an easy one. . . . Striking the right balance between safety and efficacy is especially difficult with respect to vaccines, which affect public as well as individual health.

Bruesewitz v. Wyeth, 131 S. Ct. 1068, 1079 (2011). To assert that the FDA would strike this difficult balance in favor of approving a hypothetical vaccine license application is a matter of pure conjecture. Plaintiffs provide no facts to support that conjecture and the Complaint should therefore be dismissed. *See U.S. ex rel. Ge v. Takeda Pharms. Co. Ltd.*, No. 1:11-cv-10343-FDS (D. Mass. Nov. 1, 2012), Docket Entry Nos. 43 & 44 (dismissing False Claims Act suit for failure to plead sufficient facts supporting the inference that had the FDA known of reporting violations, it would have withdrawn drug approval because "the FDA exercises discretion in its enforcement procedures"); *Barr Labs. v. Quantum Pharmics, Inc.*, 827 F. Supp. 111, 116 (E.D.N.Y. 1993) (dismissing RICO claim that depended on allegation that FDA would not have approved competitor's license application if competitor had not made false submissions, and noting that plaintiff's injury was "speculative at best" and that "[t]he FDA had discretion in deciding whether or not to issue the licenses to [the defendant]"); *see also Eli Lilly & Co. v. Roussel Corp.*, 23 F. Supp. 2d 460, 485 (D.N.J. 1998) (applying *Barr*).

Plaintiffs' Sherman Act claim simply entails too many implausible causal assumptions unaccompanied by supporting allegations.

B. Plaintiffs' Remaining State Law Claims Are Preempted by Federal Law.

Plaintiffs assert five claims under various states' laws: the Second Claim for Relief asserts violation of 25 states' unfair trade practice and consumer protections statutes; the Third Claim for relief alleges breach of contract under a state's law that they have failed to specify; the

Fourth Claim for Relief alleges breach of express warranty under Pennsylvania law; the Fifth Claim for Relief alleges breach of the implied warranty of merchantability under Pennsylvania law; and the Sixth Claim for Relief alleges unjust enrichment under a state's law that they have once again failed to specify. These claims are impliedly preempted by federal law.

Each of Plaintiffs' state law claims is based on the allegations that the vaccine's label falsely represents the efficacy rate as 95 percent, *see* Am. Compl. ¶¶ 163, 171, 180, 193, 201, and that Merck has fraudulently concealed the "true" efficacy rate from the FDA. *See, e.g.*, *id.* ¶¶ 75, 78. Plaintiffs contend that, in connection with an attempt to secure FDA "approval of a new combination vaccine that contained its Mumps Vaccine, Merck initiated new efficacy testing of its Mumps Vaccine in the late 1990s." *Id.* ¶ 7; *see also id.* ¶¶ 36, 38. They further allege Merck used a "scientifically flawed methodology," *id.* ¶¶ 7, 9, and "falsified the test data to obtain the results it desired." *Id.* ¶ 9. "Having reached the desired, albeit falsified, efficacy threshold, Merck submitted these fraudulent results to the U.S. Food & Drug Administration ("FDA"). . . ." *Id.* The end result of this supposed scheme was successful preservation of the statement of efficacy on the FDA-approved product label. Plaintiffs allege that, even though the relators in the Krahling *qui tam* case apprised the FDA of Merck's fraudulent conduct in 2001, *see id.* ¶¶ 64, 72, and the FDA conducted an on-site investigation of that charge, *see id.* ¶¶ 73-78, in 2007 the FDA approved a labeling change involving a decrease in the potency of the vaccine while leaving in place the label's statement of efficacy. *Id.* ¶¶ 92-94. The gravamen of these allegations is that Merck has been able to falsely represent the efficacy of the mumps component of its MMR vaccine by virtue of fraudulent submission of data during an FDA licensure process.

As described above and in the Krahling Motion to Dismiss (pages 21-23), Plaintiffs' claims are barred by the Supreme Court's holding that "state-law fraud-on-the-FDA claims

conflict with, and are therefore impliedly preempted by, federal law." *Buckman*, 531 U.S. at 348. Indeed, in light of the fact that the FDA has already taken whatever measures it believes are warranted by the allegations Plaintiffs make, and that those measures do not include requiring a label change, Plaintiffs' case improperly depends upon "speculation as to the FDA's behavior in a counterfactual situation." *Id.* at 354 (Stevens, J., concurring).[11] Plaintiffs' fraud-on-the-FDA state law claims are also barred by *Sandoz Pharms. Corp. v. Richardson Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990), for the reasons noted above and in the Krahling Motion to Dismiss (pages 24-26). *See also Southeast Laborers Health & Welfare Fund*, 444 F. App'x at 406-08 (barring state consumer protection claims that depended upon finding that defendant defrauded the FDA).

Plaintiffs' state law claims run afoul of other preemption doctrines as well. The statement on the product labeling concerning efficacy, which Plaintiffs assert violates state law, has been reaffirmed numerous times by the FDA, making it impossible for Merck to label the vaccine as Plaintiffs demand while still complying with its obligation to use the approved labeling. *See Fidelity Fed. Savings & Loan Assoc. v. de la Cuesta*, 458 U.S. 141, 153 (1982) ("Even where Congress has not completely displaced state regulation in a specific area, state law is nullified to the extent that it actually conflicts with federal law. Such a conflict arises when 'compliance with both federal and state regulations is a physical impossibility.'" (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142-43 (1963))). Moreover, a state law requirement that prescribing doctors should be told that the vaccine is of "dubious" or

[11] Admitting, as Plaintiffs must, a relationship between potency (the subject of the 2007 label change) and efficacy (the supposed subject of the clinical study in which Merck was engaged in fraud), *see* Am. Compl. ¶ 94, Plaintiffs have thus acknowledged that the FDA implicitly rejected the allegations that form the core of this lawsuit when the agency approved the labeling for lower potency. As detailed in the Krahling Motion to Dismiss, that rejection is also evidenced by the fact that the FDA has not asked Merck to change the labeling despite notice of the allegations in 2001 and notice of them again in 2010 with the filing of the Krahling *qui tam* action.

"questionable" efficacy, *see* Am. Compl. ¶¶ 11, 155 – a rule that would undoubtedly have the effect of dissuading doctors from using the vaccine – would stand "'as an obstacle to the accomplishment and execution of'" the long-standing federal objective of assuring widespread immunization with the very vaccine at issue in this litigation, thereby creating an additional independent basis for preemption. *See Geier v. Am. Honda Motor Co*., 529 U.S. 861, 882 (2000) (citation omitted).[12]

Federal law simply does not allow Plaintiffs to impose burdens under state law that cannot be reconciled with the FDA's exercise of its authority under the circumstances present here.

C. Plaintiffs Lack Standing to Assert Claims for Violations of 23 of the State Consumer Protection Laws They Cite and Have Not Properly Pleaded Claims Under the Statutes of the States Where They Reside.

Even if it were not preempted, Plaintiffs' claim under the consumer protection laws of various jurisdictions (Second Claim for Relief) are defective. Despite their residency in Alabama, New York, and New Jersey, respectively, Plaintiffs assert claims against Merck under the consumer protection laws of 25 different states. But they simply list in rote fashion the statutes they say Merck violated, without any attempt to allege facts supporting the elements of each state's unique statute or asserting that they purchased vaccines in those states. For this reason, Plaintiffs' Second Claim for Relief fails as a threshold matter because "this sort of 'catch all' listing of statutes does not meet the most basic pleading requirements." *In re Toshiba Am.*

[12] There can be no serious debate that nationwide immunization, including with the mumps vaccine, is an important federal objective. *See* H.R. Rep. NO. 99-908 (1986), *reprinted in* 1986 U.S.C.C.A.N. 6344, 6346 (articulating Congress's intentions in enacting the National Childhood Vaccine Injury Act of 1986 (the "Vaccine Act"), and specifically noting that "the Federal government has assumed – for more than a generation now – a leadership role in providing immunizations against childhood diseases," including mumps). Indeed, even Plaintiffs acknowledge the federal vaccination imperative, admitting that the mumps vaccine is on "the CDC's nationwide schedule of *recommended* childhood vaccinations." Am. Compl. ¶ 33 (emphasis added).

HD DVD Mktg. & Sales Prac. Litig., No. 08-939, 2009 U.S. Dist. LEXIS 82833, at *41 (D.N.J. Sept. 10, 2009) (dismissing claims based on allegations that defendants have violated the consumer protection laws of each of 44 states and the District of Columbia); *see also District 1199P Health and Welfare Plan v. Janssen, L.P.*, 784 F. Supp. 2d 508, 531 (D.N.J. 2011) (allegations that defendant violated 49 distinct state consumer protection laws failed under the controlling pleading standards).

Perhaps more fundamentally, Plaintiffs' claims based on consumer protection statutes of states other than their own fail because Plaintiffs have no standing to assert them on their own or on behalf of members of the proposed class. *See In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 156-158 (E.D. Pa. 2009) (named plaintiffs that arguably have standing in one state cannot represent absent plaintiffs from states in which the named plaintiff does not have standing); *In re Flonase Antitrust Litig.*, 610 F. Supp. 2d at 419 (because no named plaintiff had standing to bring a claim under Florida law, such claim was dismissed); *see also In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 657 (E.D. Mich. 2011) (citing cases where named plaintiffs lack standing to assert claims under the laws of the states in which they do no reside or in which they suffered no injury); *see also In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1164 (N.D. Cal. 2009) ("Where . . . a representative plaintiff is lacking for a particular state, all claims based on that state's laws are subject to dismissal.") (citation omitted); *In re Ditropan XL Antitrust Litig.*, 529 F. Supp. 2d 1098, 1107 (N.D. Cal. 2007) (same); *In re Graphics Processing Units Antitrust Litig.*, 527 F. Supp. 2d 1011, 1126-27 (N.D. Cal. 2007) (same). Because class actions do not alter substantive legal rights, *see Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 130 S. Ct. 1431, 1443 (2010), allowing a named plaintiff in a putative class action to assert claims that it personally does not have merely because it believes some other putative class

members might have those claims would be inconsistent with controlling precedent. *See Kauffman v. Dreyfus Fund, Inc.*, 434 F.2d 727, 734 (3d Cir. 1970) ("[A] predicate to [a plaintiff's] right to represent a class is eligibility to sue in his own right. What he may not achieve himself, he may not accomplish as a representative of a class.").

Even under the consumer protection statutes of the states where the named Plaintiffs reside, *i.e.*, Alabama,[13] New York, and New Jersey, and thus conceivably could have standing, Plaintiffs' claims are not properly pleaded and are defective in multiple respects.

1. Plaintiff Klein Has Not Alleged a Viable Claim Under the New York Deceptive Acts and Practices Act.

Insofar as Plaintiff Klein is purporting to assert a claim under the New York Deceptive Acts and Practices Act ("NYDAPA") on behalf of himself and other members of the putative class, that claim is flawed for numerous reasons and must be dismissed as a matter of law.

First, Klein has failed to allege any deceptive acts or practices occurring within the state of New York – a fatal omission under the Act. The NYDAPA provides: "Deceptive acts or practices in the conduct of any business, trade or commerce or in the furnishing of any service *in this state* are hereby declared unlawful." N.Y. Gen. Bus. Law § 349(a) (emphasis added); *see Weaver v. Chrysler Corp.*, 172 F.R.D. 96, 100 (S.D.N.Y. 1997) (dismissing NYDAPA claim

[13] Plaintiff Chatom, a self-described Alabama corporation, *see* Am. Compl. ¶ 12, arguably has standing to bring a claim under the Alabama Deceptive Trade Practices Act ("ADTPA"), but has chosen not to do so for good reason – the ADTPA expressly forbids class actions. *See* Ala. Code § 8-19-10(f) ("A consumer or other person bringing an action under this chapter may not bring an action on behalf of a class"); *Ex parte Exxon Corp.*, 725 So.2d 930, 933 (Ala. 1998). But even if that were not the case, any purported claim against Merck under the ADTPA would be foreclosed inasmuch as Chatom does not allege – nor could it allege within the confines of Rule 11 – that it "purchased" the Mumps Vaccine from Merck for personal, family, or household use, which is an essential element of any claim under the ADTPA. *See* Ala. Code § 8-19-3 (2) (defining "consumer" as "any natural person who buys goods or services for personal, family or household use"). Furthermore, any claim Chatom would attempt to bring under the ADTPA would fail as a matter of law for the additional reason that it did not provide a written demand for relief to Merck at least fifteen days before filing this action. *See* Ala. Code § 8-9-10(e); *Givens v. Rent-a-Center, Inc.*, 720 F. Supp. 160, 162 (S.D. Ala. 1988), *aff'd*, 885 F.2d 879 (11th Cir. 1989).

because, *inter alia*, plaintiff failed to allege any deceptive act that occurred within New York).

Second, Klein has not alleged "consumer oriented conduct" on the part of Merck, which is a basic element of a NYDAPA claim. "Consumers are 'those who purchase goods and services for personal, family or household use.'" *Med. Soc'y of State of New York v. Oxford Health Plans, Inc.*, 15 A.D.3d 206, 207 (1st Dep't 2005) (quoting *Sheth v. New York Life Ins. Co.*, 273 A.D.2d 72, 73 (1st Dep't 2000)) (citation omtited). Klein does not allege that Merck's alleged misrepresentations were intended for patients, who presumably are the ultimate consumers of mumps vaccines.[14] In fact, a key tenet of Plaintiffs' theory is that Klein and other healthcare providers were *direct purchasers* of the mumps vaccine and bought it from Merck at an inflated price (presumably before distributing it to their patients). *See* Am. Compl. at ¶¶ 12-14, 128.[15] Where, as here, the recipients of the alleged misrepresentations are sophisticated intermediaries rather than consumers, no NYDAPA claim exists because the allegedly actionable conduct is not "consumer oriented." *In re Rezulin Product Liab. Litig.*, 390 F. Supp. 2d at 339 (holding that claims by group health plans under the NYDAPA arising out of alleged misrepresentations concerning the safety of a drug were barred because the statements were not directed to consumers); *see also Black Radio Network, Inc. v. NYNEX Corp.*, 44 F. Supp. 2d 565, 583 (S.D.N.Y. 1999) (rejecting NYDAPA claim because "although plaintiffs claim that they were acting as consumers and thus should be protected by the statute, in fact this case involves businesses engaged in arm's length transactions for services that are not available to the general

[14] Even if the alleged misstatements in this case were also transmitted directly to the ultimate consumers – and there is no allegation that they were – that would not alter the analysis. *See In re Rezulin Product Liab. Litig.*, 390 F. Supp. 2d 319, 337 n.94 (S.D.N.Y. 2005) (it is "immaterial" to the "consumer oriented" action analysis that a drug is promoted directly to a potential user).

[15] If Klein or any of the other named Plaintiffs were to reverse field and somehow assert that they are not direct purchasers of the mumps vaccine, their antitrust claim would be conclusively barred by *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), which precludes an indirect purchaser from recovering antitrust damages under Clayton Act Section 4 absent special circumstances that are not present here.

public. Nor, of course, does the fact that consumers were the ultimate end-users convert the transaction into a consumer transaction."). The requirement that defendant's conduct be "consumer oriented" independently forecloses any claim by Klein against Merck under the NYDAPA.

Third, Klein has neither alleged injury to himself nor to the public interest. It is essential for a plaintiff pursuing a NYDAPA claim to allege it suffered injury as a result of the supposedly deceptive act. *See Stutman v. Chemical Bank*, 95 N.Y.2d 24, 29 (2000). It is also necessary for a NYDAPA claimant to allege "public harm" resulting from the defendant's alleged misstatements. *Maharishi Hardy Blechman Ltd. v. Abercrombie & Fitch Co.*, 292 F. Supp. 2d 535, 552 (S.D.N.Y. 2003). No such allegations are present in the Complaint. Klein does not allege that he purchased a particular dose of mumps vaccine that Plaintiffs say were of "questionable efficacy," but instead relies on boilerplate assertions that all mumps vaccines sold by Merck were substandard as the premise for his injury theory. In *Patchen v. GEICO Cas. Co.*, 759 F. Supp. 2d 241 (E.D.N.Y. 2011), the court found a similar theory of "universal inferiority" to be insufficient to establish cognizable injury under the NYDAPA in the absence of factual allegations suggesting that the products plaintiffs themselves received were deficient. *Id.* at 249-50. And even if Klein's allegation that he overpaid for less effective Mumps Vaccines had factual support – and, of course, it does not – the economic injury Klein allegedly suffered[16] could not be deemed a "public harm," especially where, as here, there is no allegation that any portion of that alleged overpayment was passed on to the patient. *See P. Kaufmann, Inc. v. Americraft Fabrics, Inc.*, 232 F. Supp. 2d 220, 226 (S.D.N.Y. 2002) (to satisfy the "public harm" element of a NYDAPA claim, acts or practices must "have a broader impact on consumers at

[16] As previously noted, the likelihood of any actual economic injury to any of the named Plaintiffs, who all are healthcare providers is small, given that reimbursement for purchase of the vaccine is available to healthcare providers from their patients, insurance companies, and/or Medicaid.

large") (citations and quotations omitted). This too precludes Klein from asserting a viable NYDAPA claim against Merck as a matter of law.

Finally, Plaintiff Klein's claim is predicated largely, if not entirely, on a theory that Merck fraudulently concealed the true results of its testing of the mumps vaccine. *See, e.g.*, Am. Compl. ¶¶ 4-11. Where, as here, Plaintiffs' claims are based on Merck's purported failure ot disclose information, Plaintiffs must plead facts demonstrating the existence of a fiduciary relationship. *See Mobil Oil Corp. v. Joshi*, 609 N.Y.S.2d 214, 215 (1994). There are no such allegations in the Complaint, which is independently dispositive of Klein's NYDAPA claim.

2. Plaintiff Sutter Has Not Alleged a Valid Claim Under the New Jersey Consumer Fraud Act.

The claims by Plaintiff Sutter under the New Jersey Consumer Fraud Act ("NJCFA") cannot be sustained for many of the same reasons that Plaintiff Klein's claim under New York law is defective. Sutter's NJCFA claim must be dismissed as a threshold matter because he is not a "consumer" with standing to invoke the statute. The NJCFA is designed to protect "consumers in the popular sense." *J&R Ice Cream Corp. v. Cal. Smoothie Licensing Corp.*, 31 F.3d 1259, 1272 (3d Cir. 1994) (citation and emphasis omitted); *see also Lemelledo v. Beneficial Mgmt. Corp.*, 696 A.2d 546, 550 (N.J. 1997) (purpose of NJCFA is "to protect consumers by eliminating sharp practices and dealings in the marketing of merchandise and real estate") (internal quotation marks and citation omitted). For a business entity, like Plaintiffs, to be "consumers" under the NJCFA, Plaintiffs must "use [economic] goods," and in so doing, "diminish[] or destroy[] [the goods'] utilities." *Cent. Reg'l Emp. Benefit Fund v. Cephalon, Inc.*, No. 09-3418, 2009 U.S. Dist. LEXIS 93636, at *7-8 (D.N.J. Oct. 7, 2009) (internal quotation marks and citation omitted); *see also In re Schering Plough Corp. Intron/Temodar Consumer Class Action*, No. 06-5774, 2009 U.S. Dist. LEXIS 58900, at *114-15 (D.N.J. July 10, 2009);

Windsor Card Shops, Inc. v. Hallmark Cards, Inc., 957 F. Supp. 562, 567 n.6 (D.N.J. 1997); *J&R Ice Cream*, 31 F.3d at 1274 (holding that plaintiff business entity was not "consumer" in connection with purchase and sale of franchise).

In this case, Sutter – a healthcare provider – does not allege that he has used or "diminish[ed] the utilities" of the mumps vaccine in his business operations. Nor does he allege that he purchased mumps vaccine for his own use and consumption. Instead, the allegations suggest that he largely serves as an intermediary between Merck and the patient receiving the vaccine. Courts interpreting the definition of "consumer" under the NJCFA have repeatedly held that persons or entities that are "middlemen" and "do not purchase drugs for the own use or consumption" cannot bring a claim under the NJCFA. *See In re Schering Plough Corp.*, 2009 U.S. Dist. LEXIS 58900, at *114-15; *see also Cent. Reg'l Employees Benefit Fund*, 2009 U.S. Dist. LEXIS 93636, at *7-8 (dismissing NJCFA claim because third party payor did not "consume prescription medications" and was thus not a "consumer" under the statute).

Plaintiff Sutter's NJCFA claim against Merck also fails as a matter of law because he has not pleaded with the specificity required by Rule 9(b) that he suffered any injury, or if he did, that such injury was caused by Merck's alleged misrepresentations. *See Frederico v. Home Depot*, 507 F.3d 188, 202 (3d Cir. 2007) (ascertainable injury and causation are essential elements of a claim under the NJCFA). In particular, the Amended Complaint is devoid of particularized factual allegations demonstrating that Sutter purchased mumps vaccine from Merck that was ineffective, and thus fails to allege injury under the NJCFA. Moreover, assuming *arguendo* that Sutter had alleged ascertainable injury, New Jersey law does not permit a NJCFA plaintiff to avoid alleging causation individually by resorting to the market-wide price inflation theory that Plaintiffs offer. *N.J. Citizens Action v. Schering Plough Corp.*, 842 A.2d

174, 178 (N.J. App. Div. 2003). Because Sutter does not allege any facts, or specific misrepresentations upon which he relied, that caused him to purchase mumps vaccine from Merck, his NJCFA claim fails as a matter of law. *See District 1199P Health & Welfare Plan*, 784 F. Supp. 2d at 531 (dismissing NJCFA claim based on lack of a "causal connection" when plaintiffs did not "plead that they received a misrepresentation of fact in deciding to prescribe" a drug).

D. Plaintiffs Fail to State Claims for Breach of an Express or Implied Warranty.

In their Fourth and Fifth Claims for Relief, Plaintiffs, citizens of Alabama, New York, and New Jersey, bring claims for breach of express and implied warranty under Pennsylvania law, 13 Pa. Cons. Stat. Ann. §§ 2313-2314. Because no named Plaintiff resides in Pennsylvania, and there is no allegation that any named Plaintiff purchased the vaccines in Pennsylvania, *see* Am. Compl. ¶¶ 12-14, Plaintiffs lack standing to bring breach of warranty claims under Pennsylvania law, and these claims must be dismissed. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d at 418-19 (stating that because "Plaintiffs cite no instance in their complaint in which they alleged that the Alabama Plaintiffs purchased Flonase in Florida" and "no named Plaintiff has alleged injury in Florida or sufficient contact with Florida, the named Plaintiffs have not stated a claim under Florida's consumer protection statute").

Even if Plaintiffs had standing, the Complaint fails to state a claim for breach of express or implied warranty.

1. Merck's Statements Regarding Efficacy Are Not Express Warranties Directed at Any Named Plaintiff.

An express warranty "arises out of representations or promises of the seller." 13 Pa. Cons. Stat. Ann. § 2313. "[E]xpress warranties are specially negotiated," and "the seller must expressly communicate the terms of the warranty to the buyer in such a manner that the buyer

understands those terms and accepts them." *Goodman v. PPG Indus., Inc.*, 849 A.2d 1239, 1243 (Pa. Super. Ct. 2004).

To create an express warranty, a representation or promise must: (a) relate to the goods; (b) be "directed at consumers in order to induce purchases of the product"; and then (c) actually become part of the "basis of the bargain." *Liberty Lincoln-Mercury, Inc. v. Ford Motor Co.*, 171 F.3d 818, 825 (3d Cir. 1999); *Sowers v. Johnson & Johnson Med., Inc.*, 867 F. Supp. 306, 314 (E.D. Pa. 1994) (citation omitted); *Yurcic v. Purdue Pharma, L.P.*, 343 F. Supp. 2d 386, 394-95 (M.D. Pa. 2004) (citations omitted); *see also* 13 Pa. Cons. Stat. Ann. § 2313(b) ("Any description of the goods which is made part of the basis of the bargain creates an express warranty that the goods shall conform to the description."). The "basis of the bargain" element requires a plaintiff to establish that "she read, heard, saw or knew of the advertisement containing the affirmation of fact or promise." *Cipollone v. Liggett Group, Inc.*, 893 F.2d 541, 567 (3d Cir. 1990), *rev'd on other grounds*, 505 U.S. 504 (1992); *see also Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 574 (E.D. Pa. 2011); *Yurcic*, 343 F. Supp. 2d at 395. Plaintiffs must allege how or by whom a promise was made, to whom it was directed, and what exactly was promised, in order to avoid dismissal. *See Kester v. Zimmer Holdings, Inc.*, No. 2:10-cv-00523, 2010 WL 2696467, at *10-11 (W.D. Pa. June 16, 2010) (dismissing breach of express warranty claim law for failure to state a claim under Pennsylvania law and Rule 8(a) as interpreted in *Twombly* and *Iqbal*); *Killen v. Stryker Spine*, No. 11-1508, 2012 WL 4482371, at *14 (W.D. Pa. Aug. 21, 2012) (same).

Here, Plaintiffs' breach of express warranty claim fails because Merck's representations regarding the efficacy of its vaccine do not create an express warranty. Plaintiffs allege Merck made representations about the efficacy of its vaccine through (a) "the package inserts of [the]

Mumps Vaccine," and (b) Merck's "marketing and advertising of Mumps Vaccine." Am. Compl. ¶ 180. First, as to the package inserts, statements contained in a label required by law cannot create express warranties. *See Sowers*, 867 F. Supp. at 314 ("[S]ince the labels at issue are required by law . . . we can infer that they were not directed at consumers and that inducing purchases was not their purpose, and that they were therefore not a part of the 'basis of the bargain' between the defendants and potential buyers.")[17]; 21 C.F.R. § 201.56(a)(1) (FDA requires that vaccine have a label "contain[ing] a summary of the essential scientific information needed for the safe and effective use of the drug"). Plaintiffs themselves concede that the label is informational only, and not intended to induce purchase: according to the Complaint, "the law requires" the label "*to inform[]* health care providers and the public of the composition of the vaccine and its overall efficacy." Am. Compl. ¶ 84 (emphasis added). The breach of express warranty claim, based on statements contained in the vaccine's label, therefore fails as a matter of law and under the facts as pleaded.[18]

Second, any statements regarding the vaccine's efficacy in Merck's "marketing and advertising" materials also fail to create an express warranty. Plaintiffs plead only the threadbare element of their claim, *i.e.*, that "Merck made the above-described representations to induce

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[17] In *Sowers*, medical equipment in a hospital was sterilized with products that are considered pesticides under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). 867 F. Supp. at 308. The products were registered with and bore a label approved by the EPA. *Id.* The court held that, because the label was required by law, it was not specifically directed at consumers to induce a purchase; therefore, representations in the label could not give rise to an express warranty under Pennsylvania law. *Id.* at 314. The court's language in *Sowers* is broad and generally applicable to any label that is required by law; indeed, *Sowers* has been applied in other settings besides pesticides regulated under FIFRA. *See Garber v. Ansell/Perry*, 63 Pa. D. & C. 4th 426, 434-35 (Pa. Comm. Pl. June 25, 2003) (finding that label, which was required by law and printed on box of latex gloves, "did not rise to the level of an express warranty . . . ").

[18] Even assuming *arguendo* that the label could create an express warranty, the MMR label at issue here is far too vague to actually create one, since it only states that the vaccine confers a high degree of protective efficacy. *See* Ex. A (MMR Label).

Plaintiffs and the members of the Class to rely on the representations and they each did so rely (and should be *presumed* to have relied)." *Id.* ¶ 182 (emphasis added). As the "benefit of the bargain" element is "essentially a reliance requirement," reliance cannot be presumed. *Sessa v. Riegle*, 427 F. Supp. 760, 766 (E.D. Pa. 1977), *aff'd*, 568 F.2d 770 (3d Cir. 1978). Yet Plaintiffs plead no facts to make plausible their conclusion that any named Plaintiff was aware of or actually relied on statements regarding efficacy contained in Merck's promotional and advertising materials, whatever those materials may be – Plaintiffs' pleading does not specify.[19] *See Yurcic*, 343 F. Supp. 2d at 395 (dismissing breach of express warranty claim because, although plaintiff alleged that statements were made generally to the public, plaintiff did not allege that he was aware of or relied on those statements). Nor do Plaintiffs allege that the advertisements or promotional materials were specifically directed at any named Plaintiff, so that statements regarding efficacy became the basis of the bargain and Plaintiffs would not have purchased the vaccine if its efficacy was anything less than 95 percent. *See Kenepp v. Am. Edwards Labs.*, 859 F. Supp 809, 817 (E.D. Pa. 1994) (express warranty must be "directed at consumers in order to induce purchases of the product") (citations omitted). Therefore, Plaintiffs' general allegations of misrepresentations in Merck's marketing and advertising fails to state a claim for breach of an express warranty. *See Killen*, 2012 WL 4482371, at *14 ("[The] Complaint does not sufficiently allege how or by whom a promise was made or what exactly was

[19] Rather than pleading the circumstances of Plaintiffs' purchase of the vaccine, the Complaint's factual allegations focus primarily on Merck's statements to the government in the course of the government's purchases of the vaccine. *See* Am. Compl. ¶¶ 87-91 (discussing statements to the FDA and European Medicines Agency ("EMA") in connection with securing approval to sell MMR in the US and the ProQuad vaccine in Europe); *id.* ¶¶ 92-95 (discussing statements to FDA in connection with a proposed labeling change for MMR); *id.* ¶¶ 95-110 (discussing statements to the government and public generally following the 2006 and 2009 mumps outbreaks). This is understandable, given that the Complaint is predicated entirely on the allegations contained in the *qui tam* action also pending on this Court's docket. Nonetheless, statements to the government and to the public at large cannot form the basis of the bargain between Merck and the named Plaintiffs in this action.

promised. Without factual support, description of a specific promise that became the basis of the bargain, or a showing that the promise was directed at her, [the] express warranty claim cannot escape dismissal.") (citation omitted).

2. The Vaccine Remains Merchantable and There Was No Breach of the Implied Warranty of Merchantability.

"[T]he implied warranty of merchantability . . . arise[s] by operation of law and serve[s] to protect buyers from loss where the goods purchased are below commercial standards." *Altronics of Bethlehem, Inc. v. Repco, Inc.*, 957 F.2d 1102, 1105 (3d Cir. 1992) (citation omitted); *see also* 13 Pa. Con. Stat. Ann. § 2314 ("[A] warranty that the goods shall be merchantable is implied in a contract for their sale if the seller is a merchant with respect to goods of that kind."); *Turney v. Media Fuel, Inc. v. Toll Bros., Inc.*, 725 A.2d 836, 840 (Pa. Super. Ct. 1999). "[I]mplied warranties are imposed by law to ensure a minimum standard of product quality and fitness, for the protection of the general public." *Goodman*, 849 A.2d at 1245.

To state a claim for breach of the implied warranty of merchantability,[20] a plaintiff must establish that the seller was a merchant, and that the goods were not merchantable at the time of sale. *Killen*, 2012 WL 4482371, at *11 (citations omitted). To be "merchantable," goods must "have an inherent soundness which makes them suitable for the purpose for which they are designed, . . . be free from significant defects, . . . perform in the way that goods of that kind should perform, and . . . be of reasonable quality within expected variations and for the ordinary purpose for which they are used." *Gall v. Allegheny Cnty. Health Dep't*, 555 A.2d 786, 789-90 (Pa. 1989) (citations omitted); *see also* 13 Pa. Cons. Stat. Ann. § 2314(b). Accordingly, a breach

[20] Plaintiffs' Fifth Claim for Relief pleads a claim only for breach of the implied warranty of merchantability under 13 Pa. Cons. Stat. Ann. § 2314. Plaintiff does not plead a claim for breach of the implied warranty for fitness for a particular purpose under 13 Pa. Cons. Stat. Ann. § 2315.

of the implied warranty of merchantability is proven through a defect in the product. *Repco*, 957 F.2d at 1105.

Here, Plaintiffs' breach of implied warranty claim fails because the vaccine was at the time of sale, and remains, merchantable. Plaintiffs allege that the vaccine's efficacy rate was less than 95 percent, but they do not allege that the vaccine was defective or that, at any lower efficacy rate (say, 94 percent), it was unable to prevent against mumps. Indeed, Plaintiffs do not allege a single instance in which one of their patients who received the vaccine contracted the mumps. "The concept of merchantability does not require that the goods be the best quality or the best obtainable but it does require that they have an inherent soundness which makes them suitable for the purpose for which they are designed . . . " *Phillips v. Cricket Lighters*, 883 A.2d 439, 444 (Pa. Super Ct. 2005) (citing *Gall by Gall v. Allegheny Cnty. Health Dep't*, 555 A.2d 786, 789-90 (Pa. 1989)) (internal citations omitted); *see also Sessa*, 427 F. Supp. at 769. Even assuming that all of Plaintiffs' allegations are true for purposes of a motion to dismiss, Plaintiffs have failed to plead that the vaccine the named Plaintiffs purchased was defective in preventing the mumps virus.

That there is no breach of an implied warranty of merchantability is further evident in the fact that the only injuries pleaded in the Complaint are economic. Plaintiffs only alleged harm is that they overpaid for the mumps vaccine, not that they or their patients contracted the disease. *See* Am. Compl. ¶ 196. Plaintiffs' general allegations regarding the 2006 and 2009 mumps outbreaks, *see id.* ¶¶ 96-110, are unconnected to any of the vaccines that Plaintiffs themselves purchased. Because there is no allegation that the vaccine performed in any way other than it should have performed for each Plaintiff – by preventing onset of the mumps virus – there is no breach of the implied warranty of merchantability.

Finally, Plaintiffs' implied warranty claim appears to be an attempt to re-cast an express warranty as an implied warranty. *See id.* ¶ 193 ("By placing Mumps Vaccine in the stream of Commerce, Merck impliedly warranted to Plaintiffs and the Class that Mumps Vaccine . . . *conformed to the promises or affirmations of fact regarding its purported 95 percent efficacy rate made on the package insert or as otherwise promoted, marketed, and/or advertised*.") (emphasis added). Therefore, the implied warranty claim also fails for the same reasons as the express warranty claim.

E. The Breach of Contract Claim Fails.

The Third Claim for Relief, for breach of contract, alleges that "Merck entered into a contract to provide Mumps Vaccine to Plaintiffs and the members of the Class," that "[t]he terms of that contract include the promises or affirmations of fact regarding the purported 95 percent efficacy rate made by Merck on the package inserts of Mumps Vaccine and through its marketing and promotion of Mumps Vaccine," and that "Merck breached these contracts because mumps vaccine does not have the 95 percent efficacy rate represented by Merck, and is in fact far less efficacious than represented by Merck." Am. Compl. ¶¶ 171, 174. The Complaint alleges that "Plaintiffs . . . were damaged in the amount of the purchase price they paid for Mumps Vaccine in addition to such incidental and consequential damages suffered as a result." *Id*. ¶ 175.

1. The Factual Allegations Do Not Support a Contract Claim.

The only allegations the Complaint makes about the vaccine purchases that allegedly constituted the contracts are that the three named Plaintiffs, who are allegedly New Jersey or New York residents, or an Alabama corporation, respectively, each purchased mumps vaccine from Merck, a New Jersey corporation doing business in Pennsylvania. Am. Compl. ¶¶ 12-15. The Complaint does not allege when any of the named Plaintiffs purchased the vaccine, how

much vaccine they purchased, or at what price. Under the law of Alabama, New Jersey, New York, or Pennsylvania, a plaintiff must allege: (1) the existence of a valid and binding contract to which he and the defendants were parties; (2) the essential terms of the contract; (3) that he complied with the contract's terms; and (4) damages resulting from the breach. *See, e.g.*, *Sweetwater Investors, LLC v. Sweetwater Apartments Loan LLC*, 810 F. Supp. 2d 1288, 1293 (M.D. Ala. 2011) (Alabama); *Berman v. Sugo LLC*, 580 F. Supp. 2d 191, 202 (S.D.N.Y. 2008) (New York); *Yapak, LLC v. Mass. Bay Ins. Co.*, Civ. No. 3:09-cv-3370, 2009 WL 3366464, at *1 (D.N.J. Oct. 16, 2009) (New Jersey); *Gundlach v. Reinsten*, 924 F. Supp. 684, 688 (E.D. Pa. 1996) (Pennsylvania). The Complaint's allegations fail to meet these elements under the law of any of these states.

To state a contract claim under the *Twombly* and *Iqbal* pleading standards, Plaintiffs must allege facts that support a plausible claim that a contract existed and was breached. In *Berman*, for example, a contract claim was dismissed where the complaint did not allege "a single fact relating to the formation of the contract, the date it took place, the contract's major terms, the parties to the contract, or [the defendant's] assent to its terms." 580 F. Supp. 2d at 202. The court explained that "[w]here, as here, the pleadings are conclusory or frame legal conclusions as factual allegations, the Court is not bound to accept them." *See id.; see also, e.g.*, *Hollingsworth v. Range Res. Appalachia, LLC*, No. 3:09-cv-838, 2009 WL 3601586, at *3 (M.D. Pa. Oct. 28, 2009) (plaintiff failed to allege facts sufficient under *Iqbal* to establish existence of contract under Pennsylvania law where the complaint did not plausibly indicate defendant's manifestation of an intent to be bound); *Yapak, LLC*, 2009 WL 3366464, at *1 (stating that "a mere recital of the elements" of a contract "will not suffice," and dismissing breach of contract claim because

failure to allege "any facts concerning the terms of the contract or the losses at issue" precludes inference that "breach of contract claim is plausible").

Here, Plaintiffs' factual allegations are far too conclusory and do not establish any of the required elements of a contract claim. The only allegations Plaintiffs make about the alleged contracts with Merck are that they "purchased" some unspecified amount of vaccine from Merck at some unspecified time and for some unspecified price. *See* Am. Compl. ¶¶ 12-14, 171, 174. The Court need not accept Plaintiffs' bare allegations that these wholly unspecified "purchases" formed a contract. *See, e.g.*, *Hollingsworth*, 2009 WL 3601586, at *3 (plaintiff must alleged facts sufficient under *Iqbal* to establish existence of contract under applicable state's law).

Plaintiffs' allegations that Merck breached any such contracts are also far too conclusory to support a contract claim. The Complaint does not allege that Merck failed to provide any of the vaccine that Plaintiffs allegedly purchased, but alleges instead that Merck breached the contracts because the efficacy of the vaccines it provided was diminished. *See* Am. Compl. ¶ 174. Plaintiffs, however, do not allege the actual efficacy rate of the vaccine they purchased. Without such an allegation, their claims that the vaccine was, variously, "far less efficacious," *id.* ¶ 174, "far less effective," *id.* ¶ 2, of "questionable efficacy," *id.* ¶ 11, of "diminished efficacy," *id.* ¶ 27, "far lower," *id.* ¶ 83, or "not as effective as Merck claims," *id.* ¶ 115, are mere conclusions. Under *Iqbal* and *Twombly*, these conclusions cannot support an inference that Merck breached the alleged contracts. *See, e.g.*, *Berman*, 580 F. Supp. 2d at 202 ("[s]tating in a conclusory manner that an agreement was breached does not sustain a claim of breach of contract") (citation omitted); *Yapak, LLC*, 2009 WL 3366464, at *1 (dismissing complaint for failure to allege defective performance adequately, and stating that allegation that defendant

breached the contract "is a legal conclusion rather than a factual allegation, and therefore the Court must disregard it").

Finally, the allegation that Plaintiffs were damaged is equally conclusory and ineffective to support the contract claim. The Complaint alleges only that the Plaintiffs were damaged "in the amount of the purchase price they paid for the mumps vaccine in addition to such incidental and consequential damages suffered as a result." Am. Compl. ¶ 175. But the Complaint alleges no facts to render this bare conclusion plausible under *Iqbal*.[21] Plaintiffs do not allege that any claim was made against them for any failure of the vaccine. Indeed, they do not allege that a single patient to whom Plaintiffs administered the vaccine contracted mumps. Plaintiffs allegations of damages cannot support a contract claim. *See, e.g., Int'l Bus. Machs. Corp. v. Dale*, No. 7:11-cv-951 (VB), 2011 WL 4012399, at *2 (S.D.N.Y. Sept. 9, 2011) ("[a]n allegation that a claimant 'suffered damages' without particular facts as to how she was damaged does not satisfy *Twombly* and *Iqbal*"); *Yapak, LLC*, 2009 WL 3366464, at *1 (no sufficient allegation of losses at issue). Because Plaintiffs do not appear to have actually suffered damage, by economic loss or otherwise, leave to amend the contract claim would be futile.

In sum, because the Complaint does not allege any, let alone all, of the elements required to state a claim for breach of contract, the contract claim should be dismissed with prejudice.

2. The Claim Should Be Dismissed for Failure to Identify the States on Whose Law the Claim Is Based.

In addition to, and consistent with, the deficiencies addressed above, the Complaint does not allege the law under which it asserts the breach of contract claim. This Court has recognized that a class action complaint based on state common law must allege the law on which it relies if

[21] As noted *supra*, Plaintiffs are healthcare providers who administer the vaccine to their patients; it is likely that Plaintiffs' pleading deficiencies are based upon the fact that, in actuality, they suffered no economic loss given that they were reimbursed for the cost of purchasing the vaccine from patients, insurance companies, and/or Medicaid.

the law of different states may differ. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d at 419 (dismissing claim with leave to amend where complaint did not identify states under whose law claim was brought). Here, the laws of different states differ with respect to their statutes of limitations for contract claims, including the length of the limitations period, when a claim for breach accrues, whether any discovery rule applies, and, if so, how it is applied. These differences are critical here because Plaintiffs' allegations strongly suggest that the contract claims of some or all of the class members may be time-barred. The Complaint alleges that Plaintiffs entered into the contracts with Merck when they purchased vaccine from 1999 to the present, and that Merck breached the contracts when it sold vaccine that was allegedly less than 95 percent effective. Thus, it appears that some claims accrued as early as 1999, well outside the limitations periods of some if not all states. Because there is a real likelihood that some or all of the putative class claims for breach of contract are time-barred as a matter of law, the breach of contract claim should be dismissed for its failure to allege which states' laws apply to the claim.

F. The Unjust Enrichment Claim Fails.

The Sixth Claim for Relief, for unjust enrichment, alleges, among other things, that "Merck has knowingly obtained benefits from Plaintiffs and the members of the Class under circumstances such that it would be inequitable and unjust for Merck to retain them." Am. Compl. ¶ 200. It alleges that "Merck has been unjustly enriched by marketing and selling its Mumps Vaccine at inflated, anticompetitive, monopoly prices," and "has collected payments" for the vaccine "that vastly exceed the payments to which Merck was entitled as a matter of law." *Id*. ¶ 200-01.

1. The Unjust Enrichment Claim Should Be Dismissed Because the Complaint Alleges That an Express Contract Covers the Subject of the Alleged Unjust Enrichment.

Under the laws of the three states where the named Plaintiffs reside or are incorporated, and also under Pennsylvania law, an unjust enrichment claim cannot stand if an express contract governs the subject of the alleged unjust enrichment. *See MT Prop., Inc. v. Ira Weinstein & Larry Weinstein, LLC*, 50 A.D.3d 751, 752 (N.Y. App. Div. 2008) (New York) ("a claim of unjust enrichment may not be maintained where there is a valid and express agreement between the parties which explicitly covers the same specific subject matter for which the implied agreement is sought") (citation omitted); *Wiseberg v. Toyota Motor Corp.*, No. 11-3776 (JLL), 2012 WL 1108542, at *11 (D.N.J. Mar. 30, 2012) (dismissing unjust enrichment claim based on sale under a contract that included specific warranty obligations; "a plaintiff may not recover on an unjust enrichment claim when there is a valid contract which governs the subject matter of the suit") (citation omitted); *Tekdoc Serv., LLC v. 3i-Infotech Inc.*, Civil Action No. 09-6573(MLC), 2012 WL 3564174, at *4 (D.N.J. Aug. 17, 2012) (New Jersey) ("It is a well settled rule that an express contract excludes an implied one. An implied contract cannot exist when there is an existing express contract about the identical subject.") (quoting *Kas Oriental Rugs, Inc. v. Ellman*, 926 A.2d 387, 392 (N.J. App. Div. 2007)); *White v. Microsoft Corp.*, 454 F. Supp. 2d 1118, 1133 (S.D. Ala. 2006) (dismissing unjust enrichment claim where plaintiff alleged breach of warranty in purchase contract; "where a plaintiff has brought claims sounding in both express contract and quasi-contract as to the same subject matter, Alabama courts have deemed the quasi-contract claims not to be cognizable"); *Gee v. Eberle*, 279 Pa. Super. 101, 420 A.2d 1050 (Pa. Super. Ct. 1980) ("[t]he doctrine of unjust enrichment is clearly 'inapplicable when the relationship between the parties is founded on a written agreement or express contract'") (citations omitted).

Because the Complaint alleges that Merck was unjustly enriched by the same matters that Plaintiff alleges to be a matter of contract, *see* Am. Compl. ¶¶ 171, 174-175, 200-201, the unjust enrichment claim cannot stand.

2. The Unjust Enrichment Claim Is Not Plausibly Alleged.

The Complaint also fails to allege unjust enrichment with the plausibility required by *Iqbal* and *Twombly*. Although the laws of Alabama, New Jersey, New York, and Pennsylvania differ on the precise elements of an unjust enrichment claim, a plaintiff must prove, at the very least, that the defendant has been unjustly enriched at the plaintiff's expense.[22] The Complaint does not sufficiently allege that element. Plaintiffs' unjust enrichment claims are based on their alleged purchases of the vaccine from Merck, but, as discussed above, Plaintiffs do not allege that they did not receive the vaccine they purchased, or that the vaccine they purchased and presumably administered to patients was not effective.[23] Because Plaintiffs have failed to allege that any enrichment was at their expense, the unjust enrichment claim should be dismissed.

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[22] *See In re Chocolate Confectionary Antitrust Litig.*, 749 F. Supp. 2d 224, 241 (M.D. Pa. 2010) (New York) (plaintiff must show (1) defendant was enriched, (2) at plaintiff's expense, and (3) the circumstances were such that equity and good conscience require the defendant to make restitution); *Wiseberg*, 2012 WL 1108542, at *10 (New Jersey) (plaintiff must allege that (1) at plaintiff's expense (2) defendant received benefits (3) under circumstances that would make it unjust for defendant to retain benefit without paying for it); *White*, 454 F. Supp. 2d at 1132 (Alabama) ("plaintiff must show that the defendant holds money which, in equity and good conscience, belongs to the plaintiff or holds money which was improperly paid to defendant because of mistake or fraud") (citations and emphasis omitted); *Clubcom, Inc. v. Captive Media, Inc.*, No. 02:07-cv-1462, 2009 WL 249446, at *9 (W.D. Pa. Jan. 31, 2009) (citing *Mitchell v. Moore*, 729 A.2d 1200, 1202 (Pa. Super. Ct. 1999)) (plaintiff must allege (1) that the plaintiff conferred a benefit upon the defendant, (2) that the defendant appreciated the benefit, (3) that the defendant accepted and retained the benefit under circumstances such that it would be inequitable for defendant to retain the benefit without payment of value).

[23] To the extent the unjust enrichment is alleged to have resulted from the alleged monopoly, the monopoly claim fails for the reasons discussed above and therefore cannot support the unjust enrichment claim.

3. The Unjust Enrichment Claim Should Be Dismissed Because the Complaint Fails to Identify the States' Laws Under Which It Is Being Asserted.

Finally, an independent reason exists to dismiss the unjust enrichment claim because Plaintiffs do not state under which state's law they are pursuing the claim. As noted above, this Court has recognized that the law of unjust enrichment may differ from state to state, and has dismissed claims for unjust enrichment when a class action complaint does not identify the law under which the claim is pursued. *See In re Flonase Antitrust Litig.*, 610 F. Supp. 2d at 419 ("[b]ecause states analyze unjust enrichment claims differently," court dismissed claim with leave to amend to state the laws under which plaintiffs were bringing the unjust enrichment claim); *see also Avenarius v. Eaton Corp.*, __ F. Supp. 2d __, 2012 WL 4903373, at *7 (D. Del. Oct. 16, 2012) (dismissing unjust enrichment claim with leave to amend where plaintiffs failed to identify the states' laws under which the claim was brought; "[g]eneric pleading and generic responsive briefing is inappropriate given that states analyze unjust enrichment claims differently"); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. at 167 (dismissing unjust enrichment claim where plaintiff did not link it "to the law of any particular state"). Because Plaintiffs have not identified the laws under which they assert the unjust enrichment claim, and because the laws of different states differ as to the claim, the claim should be dismissed.

V. CONCLUSION

For each of the foregoing reasons, the Court should dismiss Plaintiffs' Consolidated Amended Class Action Complaint against Merck in full and with prejudice.

Respectfully submitted,

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